

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

REGISTERED

To:
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**RICEVUTO
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23 LUG. 2004
BIANCHETTI-BRACCO-MINOJA srl

Date of mailing (day/month/year)	19/07/2004
PAYMENT DUE	within 30 days days from the above date of mailing
International filing date (day/month/year)	04/03/2004

Applicant's or agent's file reference
SCB 844 PCT

International application No.
PCT/EP2004/002185

Applicant
ISTITUTO NAZIONALE PER LO STUDIO E LA CURA DEI ...

1. This International Searching Authority

- (i) considers that there are 2 (number of) inventions claimed in the international application covered by the claims indicated ~~below~~ on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated ~~below~~ on the extra sheet:

- (ii) ☒ has carried out a partial international search (see Annex) ☐ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:
 see annex

- (iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

2. The applicant is hereby **invited**, within the time limit indicated above, to pay the amount indicated below:

EUR 1.550,00 x 1 = EUR 0,00
 Fee per additional invention number of additional inventions total amount of additional fees

Or, _____ x _____ = _____

The applicant is informed that, according to Rule 40.2(c), the payment of any additional fee may be made under protest, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. ☐ Claim(s) No. _____ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority
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Authorized officer

Joannes Vergoosen

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-17,19,20

ALK assay using a peptide of SEQ ID N. 1 or SEQ ID N. 2 and said peptides and related kits.

2. claim: 18

Use of compounds of formula (I) for the preparation of a medicament for the treatment of ALK-related tumors.

The present application lacks unity of invention in the sense of Rule 13.1 and 13.2 PCT.

The application as filed is considered to lack unity of invention since its subject-matter relates not to one, but rather to two separate inventions not linked together by a common underlying inventive concept as required by Rule 13.1 and 13.2 PCT.

The claims and the inventions to which the two separate inventions relate may be grouped together as follows:

Invention 1: Claims 1-17, 19, 20

Invention 2: Claim 18

According to Rule 13.2 PCT, an international patent application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features. Special technical features are such features that define the contribution of the claimed invention over the prior art.

The contributions claimed in the present application which are allegedly made over the prior art are:

a) the use of a peptide according to SEQ ID N. 1 or 2 as a substrate for ALK,

b) the use of a compound according to formula (I) to produce a medicament against an ALK-related tumour.

These contributions are not so linked to form a single general inventive concept in the sense of Rule 13.1 and 13.2 PCT. The reasons therefor are the following:

The two identified inventions involve the common concept: "(identifying) modulators of ALK activity", as the sole common link. However, this concept does not define a contribution over the prior art, because it is not new (see for example US-A-5 770 421, column 14, lines 51-58). Thus, the common concept linking the alleged inventions is not new. Therefore, there is no single general inventive concept that links the claimed inventions, which results in non-unity of invention in the sense of Rule 13.1 and 13.2 PCT.

**Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No
PCT/EP2004/002185

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
- see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rules 13.2 and 13.3 of the PCT.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim N
A	DATABASE WPI Section Ch, Week 199325 Derwent Publications Ltd., London, GB; Class A96, AN 1993-201126 XP002249142 & JP 05 126833 A (TOSOH CORP) 21 May 1993 (1993-05-21) abstract	1-17, 19, 20
A	US 5 770 421 A (LOOK A THOMAS ET AL) 23 June 1998 (1998-06-23) the whole document	1-17, 19, 20
A	WO 95/14930 A (SADICK MICHAEL DANIEL ; GENENTECH INC (US); GODOWSKI PAUL J (US); M) 1 June 1995 (1995-06-01) the whole document	1-17, 19, 20
A	WO 98/49317 A (PELES ELIOR ; ONRUST SUSAN (NZ); CLARY DOUGLAS (US); HUI TERANCE H) 5 November 1998 (1998-11-05) the whole document	1-17, 19, 20
A	WO 95/02187 A (BARKER KAREN TRACEY ; CROMPTON MARK ROGER (GB); MARTINDALE JANE ELI) 19 January 1995 (1995-01-19) the whole document	1-17, 19, 20

-/-

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

**Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No

PCT/EP2004/002185

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>SADICK M D ET AL: "Kinase receptor activation (KIRA): A rapid and accurate alternative to end-point bioassays" JOURNAL OF PHARMACEUTICAL AND BIOMEDICAL ANALYSIS 1999 NETHERLANDS, vol. 19, no. 6, 1999, pages 883-891, XP002249139 ISSN: 0731-7085 the whole document</p>	<p>1-17,19, 20</p>
A	<p>TURTURRO FRANCESCO ET AL: "Model of inhibition of the NPM-ALK kinase activity by herbimycin A." CLINICAL CANCER RESEARCH: AN OFFICIAL JOURNAL OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH. UNITED STATES JAN 2002, vol. 8, no. 1, January 2002 (2002-01), pages 240-245, XP002249140 ISSN: 1078-0432 the whole document</p>	<p>1-17,19, 20</p>
A	<p>MORRIS STEPHAN W ET AL: "ALK, the chromosome 2 gene locus altered by the t(2;5) in non-Hodgkin's lymphoma, encodes a novel neural receptor tyrosine kinase that is highly related to leukocyte tyrosine kinase (LTK)." ONCOGENE, vol. 14, no. 18, 1997, pages 2175-2188, XP002249141 ISSN: 0950-9232 the whole document</p>	<p>1-17,19, 20</p>

Patent Family Annex
Information on patent family members

International Application No

PCT/EP2004/002185

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 5126833	A	21-05-1993	NONE
US 5770421	A	23-06-1998	US 5529925 A 25-06-1996 US 6174674 B1 16-01-2001 US 6451997 B1 17-09-2002 US 2001021505 A1 13-09-2001 AU 679833 B2 10-07-1997 AU 1511695 A 19-06-1995 CA 2177957 A1 08-06-1995 DE 69433665 D1 06-05-2004 EP 0731806 A1 18-09-1996 JP 9512161 T 09-12-1997 WO 9515331 A1 08-06-1995
WO 9514930	A	01-06-1995	US 6001621 A 14-12-1999 AT 163231 T 15-02-1998 AU 697142 B2 01-10-1998 AU 1180095 A 13-06-1995 AU 698975 B2 12-11-1998 AU 1210895 A 13-06-1995 CA 2175892 A1 01-06-1995 CA 2175893 A1 01-06-1995 DE 69408541 D1 19-03-1998 DE 69408541 T2 06-08-1998 DK 730740 T3 28-09-1998 EP 0730646 A1 11-09-1996 EP 0730740 A1 11-09-1996 ES 2116066 T3 01-07-1998 GR 3026430 T3 30-06-1998 HK 1008440 A1 07-05-1999 JP 9506250 T 24-06-1997 JP 3442784 B2 02-09-2003 JP 9505889 T 10-06-1997 WO 9514776 A1 01-06-1995 WO 9514930 A1 01-06-1995 US 2002147325 A1 10-10-2002 US 2003204072 A1 30-10-2003 US 5766863 A 16-06-1998 US 6025145 A 15-02-2000 US 6287784 B1 11-09-2001 US 5914237 A 22-06-1999 US 5891650 A 06-04-1999 US 6096527 A 01-08-2000 US 5709858 A 20-01-1998 US 6087144 A 11-07-2000 US 2002137113 A1 26-09-2002
WO 9849317	A	05-11-1998	AU 7260098 A 24-11-1998 CA 2288221 A1 05-11-1998 EP 0979288 A2 16-02-2000 JP 2002513289 T 08-05-2002 US 2003073143 A1 17-04-2003 WO 9849317 A2 05-11-1998 US 6228641 B1 08-05-2001 US 2002119501 A1 29-08-2002 US 2003095970 A1 22-05-2003 US 2003008347 A1 09-01-2003 US 6342593 B1 29-01-2002

Patent Family Annex
Information on patent family members

International Application No
PCT/EP2004/002185

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9849317	A	US 6388063 B1 US 2004087783 A1	14-05-2002 06-05-2004
WO 9502187	A	19-01-1995 AU 7081094 A WO 9502187 A1 ZA 9404983 A	06-02-1995 19-01-1995 08-01-1996